EU DECLARATION OF CONFORMITY AS PER ANNEX IV OF THE REGULATION (EU) MDR 2017/745

Manufacturer:	**SAM® Medical Products** 12200 SW Tualatin Road, Suite 200, Tualatin, OR 97062, USA Tel: + 1 (503) 639-5474 | Fax: +1 (503) 639-5425 quality@sammedical.com Single Registration Number (SRN): US-MF-000002589
EU Authorized Representative:	**Emergo Europe** Prinsessegracht 20, 2514 AP The Hague, The Netherlands Tel: +31 (0)70 345 8570 emergoeurope@ul.com Single Registration Number (SRN): NL-AR-000000116
Product Family Name	SAM® Pelvic Sling II
Basic UDI-DI:	0822045SL01U6 (see details in Table 1 attached)
Device(s) concerned:	This Declaration applies to all devices and variants included within the *SAM® Pelvic Sling II Product Family* (see details in Table 1 attached).
Intended Purpose	The SAM Pelvic Sling II is a non-invasive, circumferential pelvic belt intended to stabilize pelvic fractures during transport to a definitive care facility.
Risk Class per Annex VIII:	Class I (non-sterile) as per Rule 1
GMDN Code	63496 (Pelvic binder, single use)
EMDN Code	M0305099 (Immobilization Systems and devices – Other)
Notified Body:	Not applicable. Class I (non-sterile, non-measuring, non-reusable) devices are not reviewed by a Notified body.
Conformity Assessment Route:	SAM Medical® Products utilizes Annex II and Annex III Technical Documentation (including PMS) for Class I EU medical devices and issues a Declaration of Conformity (self-certification).
Applicable CE Certificate(s):	Not applicable – Class I (non-sterile) devices are self-certified.
Standards and Common Specifications (CS):	This certificate further declares that the products covered herein also comply with the applicable requirements of relevant standards and Common Specifications specified in Table 2.

This declaration of conformity is issued under the sole responsibility of SAM® Medical Products. We hereby declare that the medical devices specified above meet the applicable provisions of the Medical Devices Regulation (EU) MDR 2017/745.

All supporting documentation is retained at the premises of the manufacturer.

Person authorized to sign on behalf of SAM® Medical Products:

Signature & date: 2021-06-23

Name: Jeff Lipps
Position: Director RA/QA, SAM® Medical Products
Place of Issue: 12200 SW Tualatin Road, Suite 200, Tualatin, OR 97062, USA

Table 1: Medical devices and variants included in the *SAM® Pelvic Sling II Product Family*

Basic UDI-DI	GTIN	Product	Packaging Level	SKU
0822045SL01U6	00822045428621	SAM Pelvic Sling II Small 27 in-45 in (69 cm-114 cm)	Each	PS300-OB-EN
	10822045428628		Case	
	00822045428638	SAM Pelvic Sling II Standard 32 in-50 in. (81 cm-127 cm)	Each	PS301-OB-EN
	10822045428635		Case	
	00822045428614	SAM Pelvic Sling II Standard 32 in-50 in. (81 cm-127 cm) – Olive Drab	Each	PS301-OD-EN
	10822045428611		Case	
	00822045428645	SAM Pelvic Sling II Large 36 in-54 in (91 cm-137 cm)	Each	PS302-OB-EN
	10822045428642		Case	

Table 2: Standards and Common Specifications (CS) applied

Standard #	Title	Year / Version
Applied Standards		
EN 1041	Information supplied by the manufacturer of medical devices	2008+A1:2013
EN ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	2020
EN ISO 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	2020
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016+AC:2018
EN ISO 14971	Medical Devices - Application of Risk Management to Medical Devices	2019
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
EN ISO 16061	Instrumentation for use in association with non-active surgical implants - General requirements	2015 See Footnote[1]
EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015+A1:2020
Other relevant standards		
EN ISO 17100	Translation services — Requirements for translation services	2015+A1:2017
ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	2015
ASTM F2503-20	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	2020
Common Specifications		
-	No common specifications relevant to the device family have been published in OJ at this time.	

[1]Annex A was utilized for biocompatibility considerations.

EUDOC-0002 SAM Pelvic Sling II DoC (Exp. 2024-06-23)

Final Audit Report 2021-06-23

Created:	2021-06-23
By:	Dan Kim (Dan.Kim@sammedical.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA4KAjvhju1cKcw7_mbjHX0GYuIzUayD83

"EUDOC-0002 SAM Pelvic Sling II DoC (Exp. 2024-06-23)" History

Document created by Dan Kim (Dan.Kim@sammedical.com)
2021-06-23 - 8:24:31 PM GMT- IP address: 50.53.248.154

Document emailed to Jeff Lipps (jeff.lipps@sammedical.com) for signature
2021-06-23 - 8:25:10 PM GMT

Email viewed by Jeff Lipps (jeff.lipps@sammedical.com)
2021-06-23 - 9:01:09 PM GMT- IP address: 50.53.248.154

Document e-signed by Jeff Lipps (jeff.lipps@sammedical.com)
Signature Date: 2021-06-23 - 9:05:29 PM GMT - Time Source: server- IP address: 50.53.248.154

Agreement completed.
2021-06-23 - 9:05:29 PM GMT